

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: GENERIC  
PHARMACEUTICALS PRICING  
ANTITRUST LITIGATION**

***IN RE: CLOBETASOL CASES***

***IN RE: CLOMIPRAMINE CASES***

**THIS DOCUMENT APPLIES TO:  
DPP BELLWETHER ACTIONS**

**MDL NO. 2724  
16-md-2724**

**DPP CASE: 16-CB-27241**

**DPP CASE: 16-CM-27241**

**OPINION**

**Rufe, J.**

**December 5, 2024**

This multidistrict antitrust litigation concerns alleged price-fixing schemes involving numerous generic drugs and generic drug manufacturers. The Court has selected as initial bellwether cases proposed class actions brought by End-Payer Plaintiffs (“EPPs”) and Direct Purchaser Plaintiffs (“DPPs”) as to two generic drugs, clomipramine and clobetasol. This Opinion considers the motions to exclude expert testimony relevant to the DPPs’ motion for class certification. Defendants have moved to exclude the opinions of two of DPPs’ experts: Dr. Thomas G. McGuire and Dr. Jeffrey J. Leitzinger. DPPs have moved to exclude the opinion of Defendants’ expert Dr. Richard J. Gilbert. The Court has considered the experts’ reports, the parties’ briefs, and the evidence and argument presented during several days of hearings.

**I. BACKGROUND**

The Court provides the background relevant to this Opinion.<sup>1</sup> DPPs include drug purchasing cooperatives and retail pharmacy operators who allege that they purchased generic

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<sup>1</sup> A fuller discussion of the allegations in the MDL may be found in the Court’s Opinions of October 16, 2018, and February 15, 2019. See *In re Generic Pharms. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 411–34 (E.D. Pa. 2018); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 820–27 (E.D. Pa. 2019).

clobetasol and clomipramine directly from Defendants. Clobetasol is a potent topical corticosteroid that is prescribed for severe inflammatory skin issues. The drug comes in five formulations: cream, emollient cream, ointment, solution, and gel.<sup>2</sup> Clomipramine is an antidepressant pill used to treat certain mental health issues, such as obsessive-compulsive disorder.<sup>3</sup>

DPPs allege that Defendants, the manufacturers of generic clomipramine and clobetasol, engaged in anticompetitive conduct that was part of a larger conspiracy or series of conspiracies involving multiple generic pharmaceutical manufacturers and multiple generic pharmaceuticals to fix, maintain, and stabilize prices and rig bids of generic drugs through market and consumer allocations of generic pharmaceutical products.<sup>4</sup> They assert federal antitrust claims under the Sherman Act.

#### **A. Clobetasol and Clomipramine Bellwether Cases**

The Court ordered the parties to begin proceedings to bring to trial, on parallel tracks, the EPP and DPP proposed class-action complaints as to clobetasol and clomipramine as bellwether cases.<sup>5</sup> Pertinent to this Opinion, DPPs have moved for class certification in the clomipramine and clobetasol cases, which Defendants oppose. DPPs seek to certify the following classes for each bellwether drug under Federal Rule of Civil Procedure 23(a) and (b)(3) with regard to their claims under federal antitrust laws:

For the Clobetasol Class,

All persons or entities that directly purchased Clobetasol (generic clobetasol propionate topical ointment .05% (15, 30, 45, or 60 gm), topical solution .05%

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<sup>2</sup> Consolidated Class Action Compl. [Clobetasol], No. 16-CB-27241 [Doc. No. 74] ¶ 1, 5.

<sup>3</sup> Consolidated Class Action Compl. [Clomipramine], No. 16-CM-27242 [Doc. No. 61] ¶ 5.

<sup>4</sup> See Consolidated Class Action Compl. [Clobetasol], No. 16-CB-27241 [Doc. No. 74] ¶ 8; Consolidated Class Action Compl. [Clomipramine], No. 16-CM-27241 [Doc. No. 61] ¶ 14.

<sup>5</sup> Pretrial Order No. 132 [MDL Doc. No. 1443].

(15 or 50 ml), topical gel .05% (15, 30, or 60 gm), topical cream .05% (15, 30, 45, or 60 gm), or topical emollient cream .05% (15, 30, or 60 gm)) from one or more of the Defendants in the United States and its territories and possessions at any time during the period from June 2014 through the present (the “Class Period”).

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities.<sup>6</sup>

For the Clomipramine Class,

All persons or entities that directly purchased Clomipramine (generic clomipramine hydrochloride 25, 50, or 75 mg capsules) from one or more of the Defendants in the United States and its territories and possessions at any time during the period from May 2013 through the present (the “Class Period”).

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities.<sup>7</sup>

DPPs and Defendants have proffered the opinions of a number of experts in the fields of econometrics and health care that bear on the question of whether the proposed classes should be certified. Accordingly, the parties filed several motions to exclude the opinions of several experts under Federal Rule of Evidence 702. The Court held hearings on these *Daubert* motions<sup>8</sup> on a selection of these experts on October 8, 2024. During this hearing, the parties presented evidence and argument regarding Dr. Richard J. Gilbert (Defendants’ witness) as well as Dr. Thomas G. McGuire and Dr. Jeffrey J. Leitzinger (DPPs’ witnesses).

## II. LEGAL STANDARD

Federal Rule of Evidence 702 provides that:

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<sup>6</sup> Consolidated Class Action Compl. [Clobetasol], No. 16-CB-27241 [Doc. No. 74] ¶ 209.

<sup>7</sup> Consolidated Class Action Compl. [Clomipramine], No. 16-CM-27241 [Doc. No. 61] ¶ 169.

<sup>8</sup> See *Daubert v. Merrell Dow Pharmas., Inc.*, 509 U.S. 579, 590 (1993).

[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.<sup>9</sup>

The focus of the Court's inquiry must be on the expert's methods, not the expert's conclusions. The Third Circuit has interpreted Rule 702 as setting forth three requirements: (1) the expert must be qualified; (2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and (3) the expert's testimony must assist the trier of fact.<sup>10</sup> “The proponent of the expert testimony bears the burden to show by a preponderance of the evidence that their expert's opinion is reliable.”<sup>11</sup> District courts have “broad discretion in determining the admissibility of evidence, and ‘considerable leeway’ in determining the reliability of particular expert testimony. . . .”<sup>12</sup>

“[A]n expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.”<sup>13</sup> An expert's opinion is reliable if it is “based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported

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<sup>9</sup> Fed. R. Evid. 702.

<sup>10</sup> *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008); *accord In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–43 (3d Cir. 1994).

<sup>11</sup> *Whyte v. Stanley Black & Decker, Inc.*, 514 F. Supp. 3d 684, 691 (W.D. Pa. 2021) (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000)).

<sup>12</sup> *Walker v. Gordon*, 46 F. App'x 691, 694 (3d Cir. 2002) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152–53 (1999)).

<sup>13</sup> *Paoli*, 35 F.3d at 742 (citing *Daubert*, 509 U.S. at 587).

speculation. . . .”<sup>14</sup> The experts must have good grounds for their opinions, but not necessarily the best grounds or unflawed methods.<sup>15</sup> Courts must consider:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.<sup>16</sup>

A court must also determine whether the expert’s testimony will assist the trier of fact—*i.e.*, it must evaluate “the ‘fit’ of the expert’s testimony as it relates to the case at hand. . . .”<sup>17</sup> The fit requirement “goes primarily to relevance.”<sup>18</sup>

### III. DISCUSSION

#### A. Dr. Richard J. Gilbert

Defendants offer Dr. Richard J. Gilbert as an expert on market structure, including economic issues related to clomipramine and clobetasol, as well as competition in the market for both bellwether drugs during the relevant period. Dr. Gilbert challenges several arguments by EPPs’ and DPPs’ experts, Dr. Lamb and Dr. McGuire.<sup>19</sup> Dr. Gilbert is a Distinguished Professor Emeritus of Economics at the University of California at Berkeley. Dr. Gilbert holds master’s degrees in electrical engineering from Cornell University and economics from Stanford

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<sup>14</sup> *Id.* (quoting *Daubert*, 509 U.S. at 590).

<sup>15</sup> See *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 784 (3d Cir. 1996); *Paoli*, 35 F.3d at 744–45.

<sup>16</sup> *Pineda*, 520 F.3d at 247–48 (citing *Paoli*, 35 F.3d at 742 n.8).

<sup>17</sup> *Macaluso v. Apple, Inc.*, No. 21-1361, 2023 WL 4685965, at \*4 (E.D. Pa. July 21, 2023).

<sup>18</sup> *Daubert*, 509 U.S. at 591.

<sup>19</sup> This Opinion addresses DPPs’ challenges to Dr. Gilbert’s opinions. EPPs’ challenges to Dr. Gilbert have been addressed in a separate Opinion.

University, as well as a Ph.D. in Engineering-Economic Systems from Stanford University.<sup>20</sup>

DPPs do not challenge Dr. Gilbert's qualifications.

In short, Dr. Gilbert provides an overview of the generic drugs market, explains the relevance of oligopolistic interdependence, explores competitive explanations for Defendants' behavior, and finds issue with multiple contentions by plaintiffs' experts. Dr. Gilbert's analysis includes criticism of EPPs' expert Dr. Lamb, although he levies the bulk of his criticisms at DPPs' expert Dr. McGuire, arguing that Dr. McGuire cannot provide a reliable basis to show evidence of an illegal agreement between Defendants.

DPPs move to exclude Dr. Gilbert's opinions in their entirety, arguing on the basis of fit and reliability that they will not help the trier of fact because they are not based on sufficient facts or data.<sup>21</sup> DPPs offer five primary arguments to support their motion for exclusion: (1) that Dr. Gilbert's opinions will not assist the jury, (2) that Dr. Gilbert's opinions are not based on sufficient facts or data, (3) that Dr. Gilbert's selective refusal to use economic theory presents an incomplete narrative, (4) that Dr. Gilbert did not disclose all of his compensation, (5) that Dr. Gilbert's EPP-related opinions should be excluded in the DPP cases.

### 1. Relevance of Dr. Gilbert's Opinions

DPPs argue that Dr. Gilbert's opinions could not assist a jury because they are irrelevant to the question of whether price hikes were the result of collusion or independent conduct. DPPs

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<sup>20</sup> See Gilbert Expert Report, EPPs' Mem. Supp. Mot. Exclude Gilbert, Ex. 2 ¶¶ 1-11, No. 16-CM-27242 [Doc. No. 228-2] (hereinafter "Gilbert Clomipramine Report"); Gilbert Expert Report, EPPs' Mem. Supp. Mot. Exclude Gilbert, Ex. 1 ¶¶ 1-11, No. 16-CB-27242 [Doc. No. 289-1] (hereinafter "Gilbert Clobetasol Rep."). Through an apparent filing error with regard to sealed documents, DPPs did not file Dr. Gilbert's expert reports on the docket. Because Dr. Gilbert's reports encompassed his opinions regarding both DPPs' and EPPs' claims, the Court cites to the EPP docket entries for the reports. Throughout the discussion as to each expert, after first reference, where the discussion encompasses both clomipramine and clobetasol documents, the Court cites the relevant clomipramine document.

<sup>21</sup> See DPPs' Mem. Supp. Mot. Exclude Gilbert at 1, No. 16-CM-27241 [Doc. No. 112]; DPPs' Mem. Supp. Mot. Exclude Gilbert at 1, No. 16-CB-27241 [Doc. No. 165].

argue that Dr. Gilbert merely states that the economic evidence—they use of which they say he criticizes in Dr. McGuire’s report—is “consistent with” independent pricing. DPPs argue that this is an unorthodox view that is not particularly probative of the question and is likely to confuse a jury because it cannot assist a jury in determining whether it is *more likely than not* that the price hikes were caused by collusion. DPPs argue that Dr. Gilbert finds that the price increases were consistent with unilateral self-interest only because he “defined away any other result.”<sup>22</sup> Dr. Gilbert, they argue, made no attempt to include whether illegal conduct in this case is more or less likely. Instead, he opines that conscious parallelism<sup>23</sup> is *possible* and then determines it was the cause with, according to DPPs, no economic analysis. DPPs indicate that this opinion should be excluded because it does little more than to summarize the record evidence.

A witness’s testimony must help the trier of fact to understand evidence offered to determine a fact at issue.<sup>24</sup> Where expert testimony is not “sufficiently tied to the facts of the case [such] that it will aid the jury in resolving a factual dispute,” it must be excluded.<sup>25</sup> The fit requirement “goes primarily to relevance.”<sup>26</sup>

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<sup>22</sup> *Id.* at 7. “As discussed above, it is well established that in the context of sequential price increases, economics does not provide any methodology or principle to distinguish conscious parallelism, or oligopolistic interdependence, from anticompetitive agreements. As a result of my review and analysis of the economic and record evidence, I conclude that the WAC increases by each of Taro, Mylan, and Sandoz are consistent with each firm acting in its unilateral self-interest.” Gilbert Clomipramine Rep. ¶ 528. DPPs argue that Dr. Gilbert’s opinion here is misleading because “[i]n a single paragraph, he postulates that economics provides no methodology to distinguish between independent and collusive conduct, but then pivots to stress that economics supports the conclusion that the defendants acted independently.” DPPs’ Mem. Supp. Mot. Exclude Gilbert at 8, No. 16-CM-27241 [Doc. No. 112].

<sup>23</sup> Dr. Gilbert uses the terms conscious parallelism, oligopolistic coordination, and recognition of oligopolistic interdependence synonymously. *See* Gilbert Rep. ¶ 13 n.5.

<sup>24</sup> *Daubert*, 509 U.S. at 591.

<sup>25</sup> *See United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

<sup>26</sup> *Daubert*, 509 U.S. at 591.

Dr. Gilbert's opinion that the evidence is "consistent with" legal oligopolistic conduct is sufficiently tied to issues in this matter that it could assist the trier of fact. Economists are not required to opine on the relative likelihood of one explanation over another for their opinions to be sound, relevant, or helpful. The trier of fact must ultimately reach the question of whether price spikes were more likely caused by legal or illegal conduct. Dr. Gilbert's opinions that the alleged price increases are consistent with independent decision-making are relevant to this question because they provide a counterpoint for DPPs' argument that the alleged price increases can *only* be explained by illegal conspiracy. Although Dr. Gilbert does not opine on the probability that legal conduct is the only or more likely answer, his analysis may be of use to the trier of fact in weighing DPPs' argument.<sup>27</sup> DPPs argue that Dr. Gilbert's opinions would confuse the trier of fact because they do not express whether legal or illegal conduct is the more probable cause of bellwether price spikes,<sup>28</sup> but this point is ultimately DPPs' burden to prove. DPPs' arguments that Dr. Gilbert's opinions are unhelpful to the ultimate question that they must prove are better made in cross-examination.

DPPs suggest that the decision in *AngioDynamics, Inc. v. C.R. Bard, Inc.*<sup>29</sup> is on point here. But Dr. Gilbert's opinions are unlike the opinions offered in *AngioDynamics*, where the Northern District of New York excluded an expert's opinions because that expert did little more than summarize the record and offered "no specialized economic analysis that would assist a

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<sup>27</sup> Tr. of Daubert Hr'g (Oct. 8, 2024) at 47-48 [MDL Doc. No. 3123] ("I think there's some evidence of conspiracy that I have called out. There's lots of other things that people claim that may or may not rise to an agreement or lack of an agreement. I can't put a probability on it, but to say that it's a mere possibility of independent behavior is a wrong conclusion. That's not my conclusion.").

<sup>28</sup> DPPs' Mem. Supp. Mot. Exclude Gilbert at 8, No. 16-CM-27241 [Doc. No. 112].

<sup>29</sup> 537 F. Supp. 3d 273 (N.D.N.Y. 2021).

fact-finder in interpreting the record evidence.”<sup>30</sup> Issues arise where an expert offers no opinion on specialized knowledge.<sup>31</sup> But the *AngioDynamics* court was careful not to apply its holding to cases involving collusion, which is alleged in the MDL. In *AngioDynamics*, the court distinguished the inadmissible opinions at issue from other cases involving unlawful collusion “in which experts have been permitted to testify as to whether conduct or market conditions reflected in the record evidence were consistent with the existence of an anticompetitive conspiracy, on the grounds that such an analysis requires specialized knowledge outside the province of an ordinary juror.”<sup>32</sup> Dr. Gilbert’s analysis employs his specialized background and is likely to assist the trier of fact.

## 2. Deviation from Standards

Next, DPPs argue that Dr. Gilbert has deviated from his own professional standard, as well as industry standards, by asserting that economics are not useful in assessing cartel conduct. Dr. Gilbert opines that “economics does not provide any clear standards to differentiate conscious parallelism from anticompetitive agreements”<sup>33</sup> and that “it is well established that in the context of sequential price increase, economics does not provide **any methodology or principle** to distinguish conscious parallelism...from anticompetitive agreements.”<sup>34</sup> An expert’s testimony must be helpful to the factfinder, and thus cannot espouse opinions that are contrary to

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<sup>30</sup> *Id.* at 333 (“Rather, he recites that evidence, draws inferences that a fact-finder could glean from merely examining the evidence itself, and concludes from those inferences that the evidence establishes causation—a conclusion a fact-finder is perfectly capable of making based on the evidence without the aid of expert testimony. Such an opinion, without more, does not pass muster under Rule 702.”).

<sup>31</sup> *Id.* quoting *Hernandez v. Leichliter*, No. 14-5500, 2016 WL 684038, at \*2, 2016 (S.D.N.Y. Feb. 18, 2016) (“To the extent [the expert] merely repeats or recasts the testimony of [the plaintiff] in order to arrive at a theory of causation, he is not testifying as an expert witness based upon specialized knowledge, but rather is acting as a conduit for another witness’s testimony in the guise of an expert’s opinion.”) (citation omitted).

<sup>32</sup> *Id.* at 334.

<sup>33</sup> Gilbert Clomipramine Rep. ¶ 13.

<sup>34</sup> Gilbert Clomipramine Rep. ¶528 (emphasis added).

law.<sup>35</sup> In the Third Circuit, courts routinely find that economic evidence is at least instructive to the question of whether illegal conspiracy behavior occurred.<sup>36</sup> The Third Circuit decision in *Valspar Corp. v. E.I. Du Pont De Nemours & Co.*, which held that “economic evidence alone” cannot be the basis for finding an agreement under Sherman Act section 1. The Third Circuit decision in *Valspar* does not go so far as to say that economic evidence has no place in determining the cause of allegedly anticompetitive behavior.<sup>37</sup>

Allowing an economics expert to opine to the trier of fact that economics cannot provide any methodology or principles to differentiate between legal and illegal conduct presents the opportunity to confuse the trier of fact and to inject issues that are contrary to Third Circuit law. As Dr. Gilbert himself agrees, “[e]conomics may have much to offer in drawing inferences from circumstantial evidence.”<sup>38</sup> Dr. Gilbert’s opinions are narrowly excluded on this point, to the extent that he expresses in his report and in testimony that economics does not provide *any* basis or principles on which to opine whether evidence is indicative of conscious parallelism and anticompetitive conduct. He is permitted, however, to opine that they do not provide “clear” or good standards to do so.

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<sup>35</sup> Fed. R. Evid. 702(a) requires that an expert’s testimony “help the trier of fact.” *See Gov’t Emps. Health Ass’n v. Actelion Pharm. Ltd.*, No. 18-3560, 2024 WL 4122123, \* 6 (D. Md. Sept. 6, 2024) (collecting cases holding that expert opinions that do not comply with applicable law are not fit under *Daubert*).

<sup>36</sup> *See In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 420 (E.D. Pa. 2015) (“The more convincing and widely followed approach allows economic experts to testify about whether certain conduct is indicative of collusion.”).

<sup>37</sup> *See Valspar*, 873 F.3d 185, 192 n.3 (3d Cir. 2017).

<sup>38</sup> Defs.’ Opp’n Mot. Exclude Gilbert, Moskowitz Decl. Ex. 1 Gilbert Dep. Tr. at 33-34, No. 16-CB-27241 [Doc. No. 175-3] (hereinafter “Gilbert Dep.”).

### 3. Factual Underpinning of Dr. Gilbert's Opinions

Next, DPPs argue that Dr. Gilbert's opinions are based on assumptions that do not fit the facts of the cases because Dr. Gilbert did not consider the meaning and implication of important evidence, including the Taro and Sandoz Deferred Prosecution Agreements ("DPAs"), the guilty plea of former pharmaceutical executive Armando Kellum, and other allegedly inculpatory material.

The existence of some contradictory evidence is not necessarily a basis on which to exclude an expert's testimony.<sup>39</sup> Further, Dr. Gilbert *has* addressed the DPAs and the guilty plea in his report.<sup>40</sup> Dr. Gilbert considers this evidence and concludes that there are gaps between their implications and the alleged conspiracies in these cases. Dr. Gilbert has also opined that such circumstantial evidence was beyond the scope of his report and opinions as an economist.<sup>41</sup> Dr. Gilbert found it inappropriate to his analysis to interpret communications between manufacturers.<sup>42</sup> To the extent that he does not treat those communications and other circumstantial evidence as dispositive, his opinions are ripe for questioning on cross-examination. His treatment of this information does not warrant exclusion under *Daubert*.

### 4. Economic and Record Evidence

DPPs take issue with Dr. Gilbert's "double standard" on economic and record evidence. According to DPPs, Dr. Gilbert's opinions are contradictory because he considers economic theory useful and discovery evidence relevant to show *parallel conduct*, but nonetheless opines

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<sup>39</sup> *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012).

<sup>40</sup> Gilbert Clomipramine Rep. ¶¶ 21-22; Tr. of Daubert Hr'g (Oct. 8, 2024) at 49 [MDL Doc. No. 3123].

<sup>41</sup> Tr. of Daubert Hr'g (Oct. 8, 2024) at 23, 49 [MDL Doc. No. 3123].

<sup>42</sup> *Id.* at 50.

that neither can be used to demonstrate *collusion* in the market. DPPs argue that Dr. Gilbert's methodology only serves to validate its preordained outcome.

Dr. Gilbert's analysis, however, is sound for purposes of *Daubert*. Typically, a disagreement between experts is better left to the trier of fact to resolve.<sup>43</sup> DPPs' experts and Dr. Gilbert disagree on the use and significance of evidence in these cases. At bottom, Dr. Gilbert opines that DPPs' cannot prove their argument that an agreement exists between competitors using only economic evidence. Dr. Gilbert's use of economic evidence in his own analysis is explained in his report and is consistent with that proposition.<sup>44</sup> Rather than disregarding record evidence, Dr. Gilbert concludes that there are gaps between that evidence and the alleged conspiracies in these cases. If Dr. Gilbert has created a "double standard," the issue goes to the weight of his opinions and are ripe for cross-examination, but they do not bear on the admissibility of his testimony.

##### 5. Compensation

DPPs argue that Dr. Gilbert did not disclose his full compensation and that this omission highlights bias in his report. On that basis, they ask the Court to exclude Dr. Gilbert's opinions. In his deposition, Dr. Gilbert testified that the actual drafting work on his report was done by members of Compass Lexecon that he supervised.<sup>45</sup> This presents a significant issue bearing on Dr. Gilbert's bias and credibility, DPPs contend, because Dr. Gilbert receives 25 percent of Compass Lexecon's total billings on these matters in addition to his own set compensation for the 50 to 100 hours of work he performed on the reports. According to DPPs' calculations, Dr.

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<sup>43</sup> See *In re Asbestos Products Liability Litigation (No VI)*, 714 F. Supp. 2d 535, 547 (E.D. Pa. 2010) (observing that "[t]he ultimate determination of whether expert testimony is correct and 'reliable' in this sense remains with the jury.") (citation omitted).

<sup>44</sup> See Gilbert Clomipramine Rep. at ¶¶ 27-32.

<sup>45</sup> Gilbert Dep. at 30.

Gilbert received an undisclosed \$750,000, or \$10,000 an hour, derived from drafting performed by other employees of Compass Lexicon in addition to his stated hourly rate of \$1,400.

Defendants counter that Dr. Gilbert *did* disclose his compensation.<sup>46</sup> If the Court requires more information, Defendants argue that the remedy is to provide that information, not to exclude his opinions. Moreover, Defendants argue that Pretrial Order No. 122 limits discovery and trial questioning on expert and consultant compensation.

Dr. Gilbert's compensation disclosure does not present a *Daubert* issue. The cases cited by DPPs were in the context of experts who failed to produce *any* indication of their compensation and failed to comply with the disclosure requirements of Federal Rule of Civil Procedure 26.<sup>47</sup> Here, Dr. Gilbert disclosed his interest in professional revenues during his deposition. Dr. Gilbert's compensation does not provide evidence of bias that would warrant exclusion under *Daubert*.<sup>48</sup>

## 6. Opinions on Dr. Lamb

DPPs argue that parts of Dr. Gilbert's report solely rebut the opinions of Dr. Russell L. Lamb, an expert for EPPs. Dr. Gilbert concludes that Dr. Lamb does not demonstrate an understanding of normal behaviors between non-conspiring oligopolists, and that Dr. Lamb incorrectly opines that Defendants' behavior can only be consistent with an illegal conspiracy. Dr. Gilbert disputes several of Dr. Lamb's opinions supporting his primary finding. Dr. Gilbert

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<sup>46</sup> Dr. Gilbert disclosed his hourly rate in his reports, but apparently did not disclose that he receives 25 percent of Compass Lexecon's total billings until questioned during his deposition. Gilbert Dep. at 217-218.

<sup>47</sup> See *Pell v. E.I. DuPont De Nemours & Co., Inc.*, 231 F.R.D. 186 (D. Del. 2005); *Dunkin' Donuts Inc. v. Patel*, 174 F. Supp. 2d 202 (D.N.J. 2001); *Adams v. Meyers Builders, Inc.*, 671 F. Supp. 2d 262, 268-29 (D.N.H. 2009).

<sup>48</sup> See *Venus v. Seville Food, LLC*, No. 14-2476, 2017 WL 2364192, at \*17 (D.N.J. May 31, 2017) (declining to exclude expert testimony based on evidence of bias and instructing defendant that to the extent it sought to challenge the expert's bias, "it is permitted to do so on cross-examination"); *In re Welding Fume Prods. Liab. Litig.*, 534 F. Supp. 2d 761, 766 (N.D. Ohio 2008) ("absent a showing of bias so extreme that exclusion is appropriate under *Daubert*, the Court believes that disclosure of possible financial bias coupled with cross-examination by the parties is a more appropriate and fine-tuned mechanism for arriving at the truth.").

argues that Dr. Lamb's finding that demand and supply shocks could not have explained generic drug price increases in this case, even if true, form no basis for Dr. Lamb's assertion that prices could not have arisen from conscious parallelism. Dr. Gilbert also finds that Dr. Lamb offers no proof for his assertion that turning down business is evidence of conspiracy by a business—and that it ignores actual incentives for independent manufacturers. Finally, Dr. Gilbert states that Dr. Lamb's assertions about the scope of information exchange between manufacturers is conclusory and unreliable.<sup>49</sup>

These opinions, DPPs argue, should be excluded because they are irrelevant to DPPs' cases. Defendants note that DPPs' objection is premature because it assumes that there will be separate trials of their cases, which the Court has not yet determined. Further, they remark that this argument has no place under *Daubert* or Rule 702 because it does not challenge the substance of Dr. Gilbert's arguments against Dr. Lamb.

The dispute fails to present a *Daubert* issue. The question of admissibility of this evidence is yet to be determined, other than on its scientific bases herein. When the Court determines how and which parties will try the bellwether cases, it may then become ripe for discussion.<sup>50</sup>

In sum DPPs' motion to exclude the opinions of Dr. Gilbert is granted in part as it relates to testimony by Dr. Gilbert that economic evidence has no bearing on determining the difference between legal and illegal interdependent conduct.

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<sup>49</sup> See Gilbert Rep. §VIII.

<sup>50</sup> The Court refers to EPPs' considerations in the concurrent EPP opinion. But it must be *strongly* emphasized that it is highly unusual for Defendants to presume that EPPs' and DPPs' claims on these two drugs would allow the Defense to present Dr. Gilbert's opinion on these experts ensemble without careful consideration of pretrial prejudice to any party.

## B. Dr. Thomas G. McGuire

Dr. Thomas McGuire is DPPs' expert on health economics. DPPs engaged Dr. McGuire to (1) assess whether methodologies can yield an opinion as to whether collusion could have raised prices for clomipramine and clobetasol, (2) assess whether Defendants' conduct was indicative of collusion, and (3) conduct a quantitative analysis of the price increases. Dr. McGuire is a Professor Emeritus of Health Economics in the Department of Health Care Policy at Harvard Medical School, where he taught in Harvard's Ph.D. program on Health Policy for 20 years. Prior to his tenure at Harvard, Dr. McGuire taught in the Department of Economics at Boston University for 25 years, teaching courses on health economics, economic theory, industrial organization, and antitrust and regulation.<sup>51</sup> Defendants do not challenge Dr. McGuire's qualifications.

Dr. McGuire frames his opinions by first stating his determination that neither demand nor supply shocks<sup>52</sup> account for the sudden increase in price for clobetasol and clomipramine. After adjusting for underlying trends in the prices of both bellwether drugs, he asserts that economic evidence supports the conclusion that Defendants' conduct is indicative of collusion. Controlling for price trends in drugs with similar market structure and similar therapeutic characteristics, he finds that economic evidence supports the conclusion that Defendants' conduct is indicative of collusion as opposed to oligopolist pricing.<sup>53</sup> He opines that it is rare to

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<sup>51</sup> McGuire Expert Report, Mem. Supp. Defs.' Mot. Exclude McGuire Ex. 1 § II, No. 16-CM-27241 [Doc. No. 93-2]; No. 16-CB-27241 [Doc. No. 143-2] (hereinafter "McGuire Rep."].

<sup>52</sup> According to Dr. McGuire, "[a] demand shock corresponds to an outward shift of the entire demand curve leading to the movement of the equilibrium price and quantity along an upward-sloping supply curve" and "[a] supply shock corresponds to an inward shift of the entire supply schedule, leading to movement of equilibrium price and quantity along a downward-sloping demand curve." McGuire Rep. ¶¶63, 71 (emphasis omitted).

<sup>53</sup> As Dr. McGuire uses the term, "parallel oligopolistic conduct" means "independent decisions by oligopolists that may result in similar market conduct." McGuire Rep. ¶ 10 n.6 (citing C. Shapiro, *Theories of Oligopoly Behavior*, 1 Handbook of Industrial Organization (R. Schmalensee and R. Willig, eds., North Holland 1989)).

see increase of this magnitude and that, if natural, those increases would have been observed in at least some other generic drugs on the market. Dr. McGuire makes two primary findings regarding the price increases for clobetasol and clomipramine: (1) that no demand or supply shocks explain price increases for both drugs and (2) collusion explains the price increases instead of legal oligopolistic behavior.

Defendants move to exclude Dr. McGuire's opinions in three areas for lack of reliability and fit: (1) that his analyses indicate that Defendants' list price increases were the product of collusion rather than oligopolistic interdependence, (2) that results of his price tests independently indicate that Defendants' list prices were the product of collusion rather than oligopolistic interdependence, and (3) that his review of the record supports his assumptions concerning the start date of the alleged conspiracies.

### 1. Economic Evidence

Defendants argue that Dr. McGuire's opinions on economic evidence for collusion are not helpful to the jury under Third Circuit precedent and must be excluded. They argue that Dr. McGuire has only shown that drug prices rose during the time period, but that he does not put forth a conclusory explanation as to the cause of those price increases. Without demonstrating a connection between price increases and an actual agreement between manufacturers, Defendants say, Dr. McGuire's opinions are not sufficient in the Third Circuit to conclude the existence of a conspiracy. Defendants further allege that Dr. McGuire neglected to consider the alternative, legal explanation for Defendants' conduct that the manufacturers worked in conscious parallelism under normal oligopolistic conditions. Defendants argue that Dr. McGuire incorrectly opines that list price increases could only result from collusion.

“[A]n expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.”<sup>54</sup> Where expert testimony is not “sufficiently tied to the facts of the case [such] that it will aid the jury in resolving a factual dispute,” it must be excluded.<sup>55</sup>

Defendants invoke the Third Circuit’s holding in *Valspar* that “economic evidence alone cannot demonstrate a tacit agreement under our oligopoly cases” to argue that Dr. McGuire’s report is not sufficient to support his opinions.<sup>56</sup> *Valspar*, they argue, holds that “any rational decision must take into account the anticipated reaction of the other firms” in an oligopoly.<sup>57</sup> Thus, Defendants contend that Dr. McGuire’s opinions on economic evidence alone are insufficient to prove that an illegal conspiracy occurred. In addition, Defendants cite the decision of the Eleventh Circuit in *Williamson Oil Co. v. Philip Morris USA*<sup>58</sup> for the proposition that courts should reject arguments that parallel price increases in an oligopoly are evidence of an illegal agreement. At most, Defendants argue that an economic expert may be permitted to argue that conduct is *consistent with* an illegal conspiracy. Thus, Dr. McGuire’s opinions that the prices can only be explained by collusion cross a “line” established in *Valspar*, according to Defendants.<sup>59</sup>

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<sup>54</sup> *Paoli*, 35 F.3d at 742.

<sup>55</sup> See *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

<sup>56</sup> *Valspar*, 873 F.3d at 19 n.3.

<sup>57</sup> *Id.* at 195 (emphasis omitted).

<sup>58</sup> 346 F.3d 1287 (11th Cir. 2003).

<sup>59</sup> Defendants argue that Dr. McGuire’s opinions have been excluded at minimum three times. See *In re Glumetza Antitrust Litig.*, 2021 WL 3773621, at \*18-19 (N.D. Cal. Aug. 25, 2021); *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at \*14-16 (S.D.N.Y. June 11, 2021); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 52 (1st Cir. 2016).

DPPs defend the strength of Dr. McGuire's opinions, and his contention that economic evidence is "indicative of" collusion. They argue that an economist's finding that something is "indicative of" a market condition was expressly adopted in *In re Processed Egg*<sup>60</sup> and thus does not cross any "line" in *Valspar*. In *In re Processed Egg*, the DPPs argue that Judge Pratter declined to follow the Eleventh Circuit's exclusion of an expert's opinion that evidence was "reflective of collusion." Instead, DPPs say that Judge Pratter's decision allows economic experts to testify about whether certain conduct is indicative of collusion. The portion of the court's opinion in *Valspar* barring "economic evidence alone," they say, is dicta that does not apply where a copious record of evidence supports a conspiracy.<sup>61</sup> Further, DPPs argue that the "economic evidence" in *Valspar* holds a narrow meaning, because in that case it referred narrowly to parallel price increases and legal "plus factors."

The Court of Appeals' decision in *Valspar* did not touch on issues of admissibility under *Daubert*. In *Valspar*, the Third Circuit approached the question of whether plaintiffs had offered sufficient proof that an agreement among competitors was the result of illegal conduct.<sup>62</sup> Applying specialized evidentiary standards at summary judgment, the Third Circuit held that plaintiffs in conspiracy cases involving oligopolies must provide certain plus factors, including non-economic evidence implying a traditional conspiracy.<sup>63</sup> The plaintiff's argument in *Valspar*, according to the Third Circuit, did not meet that standard because plaintiffs characterization of price announcements "neglect[ed] the theory of conscious parallelism" and did not attempt to

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<sup>60</sup> 81 F. Supp. at 421.

<sup>61</sup> DPPs.' Mem. Opp'n. Mot. Exclude McGuire at 7, No. 16-CM-27241 [Doc. No. 160]; DPPs.' Mem. Opp'n. Mot. Exclude McGuire at 7, No. 16-CB-27241 [Doc. No. 111].

<sup>62</sup> *Valspar*, 873 F.3d at 192.

<sup>63</sup> *Id.* at 193 ("To meet this factor, we require 'proof that the defendants got together and exchanged assurances of common action or otherwise adopted a common plan even though no meetings, conversations, or exchanged documents are shown.'").

show that parallel pricing was unusual and went beyond mere interdependence that is typical in an oligopoly.<sup>64</sup> While plaintiffs' expert opined that its "evidence excludes the inference that the competitors acted independently," the Third Circuit found that conclusion to be based on "predicates that are insufficient under our caselaw. For example, [plaintiffs' expert] took the type of evidence that we have said is of diminished value in the oligopoly context (i.e., parallel price movement and evidence best considered under the first two plus factors) and from there concluded that the suppliers had illegally conspired."<sup>65</sup> Missing in that case was "proof that the defendants got together and exchanged assurances of common action or otherwise adopted a common plan even though no meetings, conversations, or exchanged documents are shown."<sup>66</sup> In *Valspar*, the district court did not exclude the opinions of plaintiffs' expert, but ultimately rejected at summary judgment plaintiffs' arguments that relied heavily on some of that expert's testimony.

Defendants argue that *Valspar* introduces a bright line rule that experts cannot opine that a conspiracy is indicated by economic behavior.<sup>67</sup> *Valspar*, which was determined at summary judgment, creates no such standard for a court considering motions to exclude expert testimony at *Daubert*. Defendants' reliance on *Williamson Oil* is similarly misplaced. In *Williamson Oil*, the Eleventh Circuit affirmed the lower court's exclusion of an expert where that expert's opinions were not helpful because "they did not tend to make it any more probable that appellees were (or were not) engaged in a price fixing conspiracy" and because that expert "did not differentiate between legal and illegal pricing behavior, and instead simply grouped both of these

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<sup>64</sup> *Id.* at 195.

<sup>65</sup> *Id.* at 197 n.9.

<sup>66</sup> *Id.* at 193 (quoting *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 361 (3d Cir. 2004)).

<sup>67</sup> Defs.' Mem. Supp. Mot. Exclude McGuire at 11, No. 16-CB-27241 [Doc. No. 93]; Defs.' Mem. Supp. Mot. Exclude McGuire at 11, No. 16-CM-27241 [Doc. No. 143].

phenomena under the umbrella of illegal, collusive price fixing,” concluding that the expert’s testimony “could not have aided a finder of fact to determine whether appellees’ behavior was or was not legal . . . .”<sup>68</sup>

Dr. McGuire’s opinions in the present matter are quite different. Dr. McGuire’s testimony is clearly relevant to the question of determining whether price increases for clobetasol and clomipramine resulted from an illegal conspiracy among Defendants and to differentiating between legal and illegal conduct between competitors. Dr. McGuire’s methodology involves significantly more analysis than mere observation of price increases. For the bulk of his report, Dr. McGuire’s “economic evidence” consists of a number of empirical analyses that inform his opinions and constitute a more complex model than the parallel price increases and plus factors at issue in *Valspar*.<sup>69</sup> Following that analysis, he performs a series of tests that support his conclusions. Further, DPPs contend that this case includes “copious record evidence” to satisfy the traditional economic evidence plus factor that the Third Circuit found lacking in *Valspar*.<sup>70</sup> To the extent that Dr. McGuire finds that his review of evidence shows that the price increases can only be explained by collusion, those opinions do not cross the line in *Valspar*, which held that economic evidence alone cannot support a party’s argument that antitrust conspiracy occurred *at summary judgment*—not that an expert could not opine that their findings support the

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<sup>68</sup> *Williamson Oil*, 346 F.3d at 1287, 1322-23.

<sup>69</sup> Dr. McGuire examines alternative explanations for the price increase to determine that “underlying economics, data, and research studies” imply that demand shocks, supply shocks, and drug shortages fail to explain price hikes for the bellwether drugs. *See McGuire Rep.* § V. Next, he performed a series of empirical tests using variations of Defendants’ and public data to test for the difference between collusion and oligopolistic parallelism. *Id.* § VI.

<sup>70</sup> DPPs.’ Mem. Opp’n. Mot. Exclude McGuire at 7-8, No. 16-CB-27241 [Doc. No. 160]; DPPs.’ Mem. Opp’n. Mot. Exclude McGuire at 7-8, No. 16-CM-27241 [Doc. No. 111].

existence of collusion. The Court agrees with DPPs that Dr. McGuire's opinions, including his finding that common evidence is indicative of collusion, are appropriate in these cases.<sup>71</sup>

The Court need not address at this time whether Dr. McGuire's opinions on economic evidence are alone sufficient to prove that Defendants conspired to raise the prices of the bellwether drugs. Whether DPPs can prove their case on the existence and nature of potentially collusive conduct will be addressed at a later stage of litigation.

## 2. Price Tests

Dr. McGuire performs three empirical tests to distinguish between alternative explanations of collusion and independent decisions by oligopolists. As Dr. McGuire explains, each test is conducted on “different data sets with a range of specifications” and each supports his conclusion that price increases indicate collusion rather than independent decision-making.<sup>72</sup>

Defendants propose that there is an “analytical gap” between Dr. McGuire’s price-related tests and Dr. McGuire’s opinions that the price increases could only be explained by collusion. Even where an expert has offered good grounds for their opinion, that court may yet “conclude that there is too great an analytical gap between the data and the opinion proffered” if the expert’s opinions do not flow from their facts presented.<sup>73</sup> Here, however, Dr. McGuire’s tests sufficiently examine the question at hand. Throughout his initial report, Dr. McGuire explains how his tests demonstrate that price increases were likely due to collusion.<sup>74</sup>

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<sup>71</sup> See *Processed Egg*, 81 F. Supp. 3d at 420 (“The more convincing and widely followed approach allows economic experts to testify about whether certain conduct is indicative of collusion.”).

<sup>72</sup> McGuire Rep. ¶ 85.

<sup>73</sup> See *In re TMI Litig.*, 193 F.3d 613, 682 (3d Cir 1999), as amended, 199 F.3d 158 (3d Cir. 2009).

<sup>74</sup> See e.g., McGuire Rep. ¶¶ 83, 110, 148, 174, 182, 186.

Defendants further argue that, under *In re Chocolate Confectionary Antitrust Litigation*, evidence of price increases can only raise the question about whether price increases resulted from lawful or unlawful conduct.<sup>75</sup> The holding in *Chocolate Confectionary*, however, occurred at the summary judgment stage and is not instructive for a case at *Daubert*, in which the primary question is whether the expert's opinions assist the trier of fact—not whether the expert has proved a party's case.<sup>76</sup>

Defendants challenge each of Dr. McGuire's tests:

*First Test: Timing of Price Increases*

In his first test, Dr. McGuire acknowledges that oligopolies differ from firms—here, as pharmaceutical manufacturers—in perfect competition, and that those firms can raise prices without colluding with their rivals. Dr. McGuire notes, however, that several factors in these cases contribute to the likelihood that firms did collude to raise prices and were not acting as a permissible oligopoly: market structure,<sup>77</sup> barriers to entry,<sup>78</sup> inter-firm monitoring,<sup>79</sup>

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<sup>75</sup> 801 F.3d 383, 400 (3d Cir. 2015).

<sup>76</sup> *In re Processed Egg*, 81 F. Supp. 3d. at 417 (holding that an expert need only demonstrate that their methods are reliable and useful to questions addressed at class certification.).

<sup>77</sup> Measured by a three or five-firm concentration ratio or by HHI. Dr. McGuire finds that the markets for both drugs were highly concentrated, which facilitates collusion. McGuire Rep. ¶ 92.

<sup>78</sup> Dr. McGuire notes that barriers to entry are high in the generic drug market due to regulation and the resources necessary to obtain a new drug approval from FDA. McGuire Rep. ¶¶ 96-97.

<sup>79</sup> Monitoring, Dr. McGuire notes, helps firms ensure that all cartel members are sticking to the collusion. McGuire Rep. ¶ 101.

“lumpiness,”<sup>80</sup> standardization,<sup>81</sup> demand inelasticity,<sup>82</sup> multimarket contact,<sup>83</sup> and ease of direct communication.<sup>84</sup> Given his analysis of these market factors, Dr. McGuire finds that the generic drug industry is strongly characterized by market conditions that support collusive conduct.<sup>85</sup>

Defendants argue that his “Timing of Price Increases” test relies on circular reasoning because the test assumes the fact that it sets out to prove. Rather than being helpful for the trier of fact, Defendants argue that this test merely establishes that prices increased when DPPs allege a conspiracy occurred.

But Dr. McGuire adequately explains the relevance of his findings and provides good grounds for his analysis. Dr. McGuire asserts that each of his tests, including this first test, did not assume the conspiracy but treated the alleged conspiracy as a hypothesis to be tested, which he explains is standard procedure in an empirical inquiry in economics and other fields.<sup>86</sup>

Describing each of his empirical tests, Dr. McGuire explains:

The *hypothesis* of independent decisions leading to nearly simultaneous sharp price increases contains no prediction about when such decisions leading to sharp price increases would occur or for which drugs. If this *hypothesis* were correct, we should expect to see nearly simultaneous sharp price increases occurring for other drugs and at times outside the Start Periods. By contrast, the *hypothesis* that collusion occurring during the Start Periods was the cause of the sharp price increases does predict when the increases would occur, i.e., during the Start

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<sup>80</sup> Dr. McGuire says that “lumpiness” refers to the large volume of sales that take place during a particular transaction. This makes collusion more difficult to sustain because gains from deviating from a strategy are large. McGuire Rep. ¶¶ 102-03.

<sup>81</sup> The more standardized a product is, Dr. McGuire indicates the more likely it is that firms will agree on a common price structure. McGuire Rep. ¶ 104.

<sup>82</sup> Percentage change in quantity demanded associated with change in price. Collusion is more profitable where demand is inelastic, although it can make the product more sensitive to supply shocks. McGuire Rep. ¶¶ 105-08.

<sup>83</sup> When firms compete across markets, including for other generic drugs. Dr. McGuire indicates that the Defendants compete for a large percentage of their products. McGuire Rep. ¶ 109.

<sup>84</sup> Collusion is more likely if the competitors know each other through social channels, and Dr. McGuire asserts that witnesses in this MDL have indicated that they communicate with one another in the industry. McGuire Rep. ¶ 110.

<sup>85</sup> McGuire Expert Rebuttal Rep., DPPs.’ Opp’n. Summ. J. Ex 121 ¶ 70, No. 16-CM-27241 [Doc. No. 159-119] (hereinafter “McGuire Rebuttal Rep.”).

<sup>86</sup> McGuire Rebuttal Rep. ¶70.

Periods. Observing sharp price increases for the Bellwether Drugs during the Start Periods but not or infrequently at other times or for other drugs constitutes strong evidence that the price increases were indicative of collusion.<sup>87</sup>

Dr. McGuire explains that the evidence could have fallen either way, citing literature that an expert's hypothesis is meaningful if it is capable of falsification.<sup>88</sup> Dr. McGuire's first test does not rely on circular reasoning and is helpful to the trier of fact because the results could have borne out to demonstrate an alternative conclusion.

*Second Test: Control Group*

In his second test in relation to other drugs on the market, Dr. McGuire introduces control drugs to capture trends in pricing not related to collusion. First, Dr. McGuire compares each bellwether drug to control drugs with similar market characteristics.<sup>89</sup> Next, Dr. McGuire compares the drugs to other drugs with similar therapeutic characteristics.<sup>90</sup> He used IQVIA<sup>91</sup> data to identify a set of control drugs with similar market structure to the Bellwether drugs.<sup>92</sup>

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<sup>87</sup> McGuire Rep. ¶ 84 (emphasis added).

<sup>88</sup> McGuire Rebuttal. Rep. ¶ 71 n.90.

<sup>89</sup> McGuire Rep. § VI.C.

<sup>90</sup> McGuire Rep. § VI.D.

<sup>91</sup> IQVIA is healthcare consulting and analytics company that provides data to the life sciences industry. Entities use data from IQVIA to measure market and product demand. *See Prescription Information*, IQVIA, <https://perma.cc/W8K7-2QZ3>.

<sup>92</sup> For each drug, this includes three sets of drugs. For **clomipramine**:

Set A were those with a three-firm concentration ratio greater than 80%, a one-firm concentration ratio between 60% and 80%, and 2011 sales between 50% and 300% of clomipramine sales. Set B loosens the sales criterion. Set B has the same concentration ratios but includes drugs with no upper limit on sales. Set C loosens the concentration ratio criterion. Set C control drugs are those with a three-firm concentration ratio greater than 70%, a one-firm concentration ratio between 50% and 90%, and no upper limit on sales. In total there were 22 control drugs in Set A, 54 in Set B, and 135 in Set C for clomipramine.

For **clobetasol**:

Set A drugs were those with a three-firm concentration ratio greater than 50%, a one-firm concentration ratio between 10% and 50%, and 2011 sales between 50% and 300% of clobetasol. Set B keeps the same concentration ratios but removes the upper sales limit. Set C loosens the concentration-ratio constraints to include drugs with a three-firm concentration ratio greater than

Defendants argue that Dr. McGuire's "Control Group" tests are improperly based on damage models rather than models designed to test liability. They assert that Dr. McGuire's selection methodology and modeling rely on scholarly articles that address *damages* calculations, not causation.<sup>93</sup> Defendants further argue that the law distinguishes between models for causation and those for damages, and claim that Dr. McGuire's test, too, is circular because it presupposes the price fixing that it sets out to prove.

Dr. McGuire, however, indicates that the models he relies on are not damages models in the "legal sense."<sup>94</sup> Rather, Dr. McGuire says that the papers he relies on use damages in an economic sense to refer to elevated prices.<sup>95</sup> Those models still tested for collusion, according to Dr. McGuire's assessment.<sup>96</sup> Regarding the circularity of Dr. McGuire's reasoning, here, again, Dr. McGuire indicates that he tested the hypothesis of independent action.<sup>97</sup>

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40%, a one-firm concentration ratio between 0% and 60%, and no upper sales limit. In total there were 2 control drugs in Set A, 6 in Set B, and 14 in Set C for clobetasol.

<sup>93</sup> See McGuire Rep. ¶¶ 140-41 (internal citations omitted).

<sup>94</sup> Defs.' Mem. Supp. Mot. Exclude McGuire at 18.

<sup>95</sup> See McGuire Dep. Tr., Defs.' Mem. Supp. Mot. Exclude McGuire Ex. 2 at 205, No. 16-CM-27241 [Doc. No. 93-3]; McGuire Dep. Tr., Defs.' Mem. Supp. Mot. Exclude McGuire Ex. 2 at 205, No. 16-CB-27241 [Doc. No. 143-3] (hereinafter "McGuire Dep.").

<sup>96</sup> *Id.* at 207.

<sup>97</sup> *Id.* at 207-08 ("[Discussing the working paper "Does Entry Remedy Collusion? Evidence from the Generic Prescription Drug Cartel" by Amanda Starc and Thomas G. Woolmann] I'd say [the authors] treat[] [allegations of alleged collusion] in the same way that [an article titled "Collusion in the U.S. Generic Drug Industry" by Robert Clark et. al] did, which is these are -- I want to set these drugs aside, because they've been alleged to be the subject of the collusion and used to estimate and model the other drugs, the ones that are broadly in a kind of control group that she uses. And then [the authors] empirically assess[], [The authors] say[], 'Okay, let me not just make an assumption about damages. Let me test the degree to which prices are elevated according to the way my model says pricing should work in comparison to what you actually observe in the drugs that are subject to a conspiracy.' So that's not an assumption. That's a test.").

<sup>98</sup> McGuire Rep. ¶ 84.

*Third Test: Conditional Probability*

In his third test, on “Conditional Probability,” Dr. McGuire argues that the price hikes following the start periods are a “(Super) Plus Factor.” As Dr. McGuire explains, a “plus factor” is “evidence that tends to exclude the possibility that the defendant’s actions were merely interdependent.”<sup>98</sup> A plus factor is an action that is inconsistent with unilateral conduct that allows inference of an agreement. Courts typically look to various “plus factors” in antitrust cases to distinguish legal conscious parallelism from illegal price-fixing agreements.<sup>99</sup> Dr. McGuire opines that some plus factors are “super” plus factors because they are so powerful that they, on their own, make the likelihood of collusion very high.<sup>100</sup> Dr. McGuire based his Conditional Probability test on an article by William Kovacic, et al., which assumes that a single form of evidence that pushes the likelihood of collusion past 90 percent is a “super” plus factor that courts should afford significant weight.<sup>101</sup> He studies this supposed “super” plus factor using three data inputs: (1) frequency of simultaneous price spikes for the Bellwether drugs at the start period, (2) frequency of large price spikes for other similar drugs, and (3) the likelihood that the research believes collusion is present, based on empirical evidence or industry experience, before new evidence is introduced.<sup>102</sup> Dr. McGuire finds that, for the observed time, none of the drugs he observed except the bellwether drugs experienced price spikes of more than 200 percent.<sup>103</sup> Applying the rules for his Conditional Probability test, Dr. McGuire finds that

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<sup>98</sup> McGuire Rep. ¶ 12 n.10.

<sup>99</sup> See *Baby Food*, 166 F.3d at 122.

<sup>100</sup> McGuire Rep. ¶ 172.

<sup>101</sup> McGuire Rep. ¶ 181.

<sup>102</sup> McGuire Rep. ¶ 180-82.

<sup>103</sup> McGuire Rep. § VI.E.

price spikes for the bellwether drugs indicated collusion by over 99 percent, surpassing the 90 percent threshold to qualify as a “super” plus factor.<sup>104</sup>

Dr. McGuire’s Conditional Probability test, Defendants argue, is not a reliable methodology because it fails the *Valspar* standard that economic evidence is insufficient to infer the existence of a conspiracy. But for the reasons stated above, the Court does not agree with Defendants’ reading of *Valspar*. Further, Defendants say that Dr. McGuire’s reliance on the Kovacic, et al. article that underlies the test is unreliable because the test has been rejected in litigation. The case they cite, *Anderson News, L.L.C. v. American Media, Inc.*, does not reject the conditional probability test, but rather finds that the expert at issue in that case did not have sufficient basis to establish the term “super-plus factor” or to describe any plus factor as “super.”<sup>105</sup> The Court agrees with *Anderson News*’s holding on that point—Dr. McGuire may opine on plus factors, and the confidence he has in his opinions on those plus factors’ strengths—but neither DPPs or Dr. McGuire prove that the term “super-plus factor” is generally accepted in the scientific community.<sup>106</sup> Therefore, Dr. McGuire’s testimony is excluded as to the narrow point that conditional probability is a “super” plus factor.

### 3. Review of the Record

Defendants argue that Dr. McGuire’s review of evidence was cherry-picked and that he indicated in his deposition in this matter that he “look[ed] for evidence that’s consistent with the assumption [he] was asked to make.”<sup>107</sup> Thus, Defendants say that Dr. McGuire failed to

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<sup>104</sup> McGuire Rep. ¶ 181.

<sup>105</sup> 2015 WL 5003528 at \*3 (S.D.N.Y. Aug. 20, 2015).

<sup>106</sup> *See id.*

<sup>107</sup> Defs.’ Mem. Supp. Mot. Exclude McGuire at 23, No. 16-CB-27241 [Doc. No. 93]; Defs.’ Mem. Supp. Mot. Exclude McGuire at 23, No. 16-CM-27241 [Doc. No. 143].

consider contrary evidence. DPPs argue that Dr. McGuire's treatment of the factual record in Section VII of his report has the narrow purpose of "test[ing] the reasonableness of [his] assumptions about the Start Periods." DPPs argue that his use of the factual record is a matter for cross examination, not for a *Daubert* motion.

The district court in *In re Processed Egg* rejected a motion to exclude the testimony of an expert on the basis that he had not considered all facts in the record where evidence in the case was voluminous, holding that the contention went to the weight of testimony, not its admissibility, in part because "Finally, the Court rejects Defendants' contention that [the expert's] testimony should be excluded because he failed to consider certain aspects of the record. The briefing and arguments have not revealed that [the expert's] failure to include certain facts in his analysis was so egregious as to make his methodology unreliable. This contention goes to the weight of [the expert's] testimony, not its admissibility. The record in this case is voluminous, to say the least, and no expert will be able to include every document in his analysis."<sup>108</sup> The same can be said here, and the existence of some contradictory evidence is not necessarily a basis on which to exclude an expert's testimony.<sup>109</sup>

In this MDL, discovery has produced millions of documents for experts to wade through and the Court does not expect that experts have examined them all. Defendants liken Dr. McGuire's use of the record to a case in which the Court excluded an expert opinion that failed to adequately account for scientific evidence that directly contradicted her findings.<sup>110</sup> Dr. McGuire's analysis is unlike the problematic expert analysis in *In re Zoloft (Sertraline*

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<sup>108</sup> *In re Processed Egg Prods.*, 81 F. Supp. 3d at 425.

<sup>109</sup> *ZF Meritor*, 696 F.3d at 290 (noting that the credibility of respective experts is a question for the jury).

<sup>110</sup> Defs.' Mem. Supp. Mot. Exclude McGuire at 22, No. 16-CB-27241 [Doc. No. 93]; Defs.' Mem. Supp. Mot. Exclude McGuire at 22, No. 16-CM-27241 [Doc. No. 143].

*Hydrochloride) Product Liability Litigation*, a products liability case in which the Court excluded an expert opinion that failed to adequately account for scientific evidence that directly contradicted her findings.<sup>111</sup> The Court has addressed a similar argument regarding EPPs' expert. As explained in that opinion, *Zoloft* can be differentiated here:

In [*Zoloft*], an expert opining on causation impermissibly neglected to consider information, including some of her own peer-reviewed studies, that may have greatly affected the outcome of her methodology. Causal conclusions require examination of the literature of a field as a whole, but the expert in *Zoloft* neglected to include concerning swaths of pertinent literature. The omitted evidence, if included, may have drastically changed that expert's opinions. The present matter is quite different.<sup>112</sup>

Dr. McGuire's task in this matter was to find evidence about the reasonableness of the assumptions he was asked to make with respect to the start date of the conspiracy, not to present a scientific opinion.<sup>113</sup> Dr. McGuire reviewed an abundance of record evidence in this case and the material that he did not include does not materially affect his findings.

Further, none of the examples of supposed omissions undermines the reliability of Dr. McGuire's opinions as a matter of law. Dr. McGuire's opinions are not necessarily rendered unreliable by discrete examples that may not confirm his findings. Where Dr. McGuire has been confronted with those examples, he provides sound explanations regarding why they do not change his opinion, usually explaining that those instances reflect the thoughts, opinions, or actions of only a few individuals at a point in time but are not illustrative of the record evidence as a whole.

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<sup>111</sup> 26 F. Supp. 3d 449 (E.D. Pa. 2014).

<sup>112</sup> See *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, 2024 WL 4980784 at \*9 (E.D. Pa. Dec. 3, 2024).

<sup>113</sup> See DPPs.' Mem. Opp'n. Mot. Exclude McGuire at 15, No. 16-CM-27241 [Doc. No. 160]; DPPs.' Mem. Opp'n. Mot. Exclude McGuire at 15, No. 16-CB-27241 [Doc. No. 111].

Defendants' motion to exclude the opinions of Dr. McGuire is denied in part and granted to the extent that Dr. McGuire opines that his conditional probability test demonstrates the existence of a "super" plus factor.

### **C. Jeffrey J. Leitzinger**

Dr. Jeffrey J. Leitzinger is DPPs' economics expert to estimate aggregate overcharges for each of the proposed direct purchaser classes, analyze the extent to which each of those buyers paid inflated prices due to Price Spikes,<sup>114</sup> and develop a method to allocate aggregate damages awards to members of each class for the DPP clobetasol and clomipramine cases.<sup>115</sup> Dr. Leitzinger is an economist and Managing Director at Econ One Research, Inc., an economic research and consulting firm. He holds master's and doctoral degrees in economics from UCLA.<sup>116</sup> Defendants do not challenge Dr. Leitzinger's credentials.

Dr. Leitzinger explains that he used transaction-level purchase data from Defendants to determine the actual amounts paid by clomipramine and clobetasol class members, as well as purchase volume. Of the class members for which he has data, Dr. Leitzinger concludes that virtually all of them paid inflated prices due to Defendants' conduct.<sup>117</sup>

Defendants move to exclude Dr. Leitzinger's opinions in their entirety, arguing that they are not reliable or fit for this case. Despite admitting that Dr. Leitzinger has extensive expertise in the pharmaceutical industry, Defendants argue that his two-stage methodology in this case is

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<sup>114</sup> Price Spikes refer to "large price increases beginning in May 2013 for clomipramine and June 2014 for clobetasol." For his report, Dr. Leitzinger assumes that these increases were the product of illegal conspiracies among Defendants. Leitzinger Expert Report, Harrell Decl. Ex A ¶ 7, No. 16-CM-24241 [Doc. No. 94-2]; No. 16-CB-24241 [Doc. No. 144-2] (hereinafter "Leitzinger Rep.").

<sup>115</sup> Leitzinger Rep. ¶ 7.

<sup>116</sup> Leitzinger Rep. ¶ 1.

<sup>117</sup> Leitzinger Rep. ¶ 9.

untested, drawn on datasets that are not appropriate to estimate damages, and improperly rely on averages to create a single but-for price. Defendants argue that there are three key faults with the reliability of Dr. Leitzinger's model: (1) that his two-stage regression overcharge model is unreliable, (2) that his overcharge model is not tied to each of plaintiffs' theories of anticompetitive conduct, and (3) that his model is not based on any scientific methodology or specialized knowledge.<sup>118</sup>

### 1. Regression Model

In order to reach his conclusions, Dr. Leitzinger employs a two-stage regression model. Defendants claim that Dr. Leitzinger's "two-stage" regression analysis is untested and unreliable at each stage.

In Stage One, Dr. Leitzinger's model uses IQVIA data over time for generic drugs outside of the conspiracy to estimate normal market relationships between 3,400 generic drugs and normal market factors.<sup>119</sup> Dr. Leitzinger's model accounts for various independent variables as explanatory factors.<sup>120</sup> As a result, Dr. Leitzinger finds that his model explains approximately 95 percent of the variation in generics prices.<sup>121</sup>

In Stage Two of his model, Dr. Leitzinger uses a regression model of Average Manufacturer Prices (AMPs)<sup>122</sup> for each of the Bellwether drugs on the prices predicted in Stage

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<sup>118</sup> Defendants emphasize that Dr. Leitzinger has not employed this type of model in any other pharmaceutical case. According to Defendants, "regression modeling is only reliable to the extent it is properly employed," and argue that Dr. Leitzinger does not have good grounds for each step. Defs.' Mem. Supp. Mot. Exclude Leitzinger at 9, No. 16-CM-27241 [Doc. No. 94]; Defs.' Mem. Supp. Mot. Exclude Leitzinger at 9, No. 16-CB-27241 [Doc. No. 146].

<sup>119</sup> Leitzinger Rep. § A.1.

<sup>120</sup> These variables are identified as market size, clinical prevalence of the drug, producer price index, number of manufacturers, market concentration, brand indicator, time on the market, generic share (higher generic shares likely correspond to lower prices), generic drug user fee amendments drug fixed effects, and time fixed effects. Leitzinger Rep. ¶ 38.

<sup>121</sup> Leitzinger Rep. ¶ 39.

<sup>122</sup> According to Dr. Leitzinger, "The AMP is 'the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.'" Leitzinger Rep. ¶ 13 (citing 42

One.<sup>123</sup> The purpose of this model, Dr. Leitzinger explains, is to isolate “the part of the Price Spike for each of the bellwether drugs that cannot be explained either by the systemic price relationships captured within the Stage One industry model or by other factors that are specific to these drugs.”<sup>124</sup> To calculate the expected price movements for each drug, he applies Stage One’s coefficient estimates to reflect predicted changes in price associated with the market. His model considers possible explanations for the price increases.<sup>125</sup> Dr. Leitzinger does not find evidence that the Bellwether drugs showed changes over time for non-conspiracy market factors, other than costs.

Dr. Leitzinger acknowledges that his model includes multiple sensitivities that could change his overall overcharge findings: that he omits from the data certain generic drugs that DPPs alleged were affected by the conspiracies, that his Stage One model uses only drugs with the same Uniform System of Classification 3 category in IQVIA as the bellwether drugs, and that changes in health insurance could alter his findings on the share of prescription drug spending. For each of those potential weaknesses, he finds that the inclusion of those factors does not change his results in a statistically meaningful way.<sup>126</sup>

An expert’s conclusions must be “supported by good grounds for each step in the analysis,” meaning “*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible, . . . whether the step completely changes a reliable

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CFR § 447.504; Christine Provost Peters, Medicaid Payment for Generic Drugs: Achieving Savings and Access [Internet], Washington (DC): National Health Policy Forum (Sept. 30, 2010) <https://perma.cc/8963-YVCU>.

<sup>123</sup> Leitzinger Rep. § B.1.

<sup>124</sup> *Id.*

<sup>125</sup> Dr. Leitzinger looks at supply disruptions (he states that the FDA’s database shows no records of shortages for either drug in 2013 or 2014), demand changes (he finds no evidence of increases in demand for either drug), and brand prices (he does not find any brand increases outside of the alleged conspiracy). Leitzinger Rep. ¶ 46.

<sup>126</sup> Leitzinger Rep. § VII.C.

methodology or merely misapplies that methodology.”<sup>127</sup> Exclusion is only required where “the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury. . . .”<sup>128</sup>

First, Defendants point out that Dr. Leitzinger has not previously employed the model he uses in this case in any other generics case in which he has participated. Dr. Leitzinger clarifies that he has not previously employed the “specific calculations and the sources of information” that he used in this case.<sup>129</sup> While he has never used this data in similar circumstances, Dr. Leitzinger explains that other generics cases in which he has offered his opinion have not touched on the same issues because his previous work has been in generics entry cases. DPPs explain that conduct in a generics entry case is distinct from the conduct alleged here, and thus Dr. Leitzinger took a different approach to address a different type of conduct.<sup>130</sup> The common thread between his previous work in this case, as Dr. Leitzinger describes, is not the type of model he employs, but that each involves his determination on the “difference between prices that were paid and prices that would have been paid under some alternative course of conduct.”<sup>131</sup> The more pertinent question is whether Dr. Leitzinger’s methodology runs afoul of standard practices or accepted literature in the field. To that end, Defendants contest each facet of Dr. Leitzinger’s model. Accordingly, the Court considers the validity of each step of Dr. Leitzinger’s model.

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<sup>127</sup> *Paoli*, 35 F.3d at 745 (footnote and emphasis omitted).

<sup>128</sup> *Sterling v. Redevelopment Auth. of City of Phila.*, 836 F. Supp. 2d 251, 271–72 (E.D. Pa. 2011) (quoting *Child. ’s Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004)).

<sup>129</sup> Leitzinger Dep. Tr., Harrell Decl. Ex B at 314; No. 16-CM-24241 [Doc. No. 94-3]; No. 16-CB-24241 [Doc. No. 144-3] (hereinafter “Leitzinger Dep.”).

<sup>130</sup> DPPs’ Mem. Opp’n Mot. Exclude Leitzinger at 20, No. 16-CM-27241 [Doc. No. 110]; DPPs’ Mem. Opp’n Mot. Exclude Leitzinger at 20, No. 16-CB-27241 [Doc. No. 163].

<sup>131</sup> Leitzinger Dep. at 314.

*Stage One*

First, Defendants assert that Dr. Leitzinger's Stage One regression is not relevant or reliable because his model does not study market factors on pricing for clobetasol and clomipramine (or drugs that treat similar conditions or have the same formulation), or other products manufactured by Defendants in the bellwether cases. Instead, Defendants argue that Dr. Leitzinger's analysis examines the market for drugs that are irrelevant in this case. It is not significant, they argue, that Dr. Leitzinger's model reliably explains 95 percent of the price variation for generic products if it does not assess the products at issue.

Dr. Leitzinger's analysis in Stage One of his model is founded on good grounds. Dr. Leitzinger's use of IQVIA data is well-supported and common in the pharmaceutical industry.<sup>132</sup> Here, Dr. Leitzinger used IQVIA pricing data to study the relationship between unrelated generic drugs and the broader market—not to estimate pricing data for clomipramine and clobetasol.<sup>133</sup> Defendants argue that Dr. Leitzinger's sample of 3,400 drugs are irrelevant because they can only predict pricing for *those* products, not for the bellwether drugs. Further, Defendants argue that his sample pool is too large and that many of the included products share little similarity with the bellwether products. But Dr. Leitzinger opines that this is a function, not a fault, of his analysis: “part of what the model does is take advantage of differences in the markets that are reflected in those 3,400 drugs...[so that] I can then use that to analyze the potential impact of any structural changes that occurred for the products in question.”<sup>134</sup> Further, Dr. Leitzinger's choice

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<sup>132</sup> DPPs refer to IQVIA data as the “gold standard of data showing how [market factors] operate....” See Tr. of Daubert Hr’g (Oct. 8, 2024) at 163-64 [MDL Doc. No. 3123]. Other courts have similarly found data produced by IMS to be the gold standard in calculating damages on behalf of TPPs. See *In re Actiq Sales & Mktg. Pracs. Litig.*, 2014 WL 3572932, at \*10 (E.D. Pa. July 21, 2014) (collecting cases).

<sup>133</sup> DPPs’ Mem. Opp’n Mot. Exclude Leitzinger at 5, No. 16-CM-27241 [Doc. No. 110]; DPPs’ Mem. Opp’n Mot. Exclude Leitzinger at 5-6, No. 16-CB-27241 [Doc. No. 163]; Leitzinger Rep. ¶¶ 37-38, 40.

<sup>134</sup> Leitzinger Dep. at 184-85.

of drugs for comparison does logically tie to market conditions for the bellwether drugs. In Stage One, Dr. Leitzinger uses drugs within the same IQVIA USC, which groups pharmaceutical products that compete in the same or similar markets.<sup>135</sup> Drugs that share the same market as the bellwether drugs are a logical comparison for Dr. Leitzinger's Stage One analysis, which purports to measure market differences. Defendants may disagree with Dr. Leitzinger's approach here and the data he uses to draw his conclusions, but they do not cite literature to support that his methodology or data selection is devoid of scientific analysis or outside of the norm in this field.

Stage One of Dr. Leitzinger's analysis has potential, with the rest of his model, to assist the trier of fact. As a means to predict expected prices for a generic drug, generally, Dr. Leitzinger's model is highly effective.<sup>136</sup> Although by itself it cannot provide a basis for liability or damages, Stage One achieves its purpose of estimating the relationships between non-collusive market conditions and generic drug prices, generally.<sup>137</sup> Dr. Leitzinger's Stage One methodology passes *Daubert*'s threshold of reliability.

#### *Stage Two*

Defendants levy a number of challenges to Dr. Leitzinger's Stage Two model.

First, Defendants challenge Dr. Leitzinger's model for its use of AMP and IQVIA data, asserting that it fails to reflect "actual" prices paid by class members and because it relies on average data that obscures differences among individual purchasers. DPPs contend that Dr. Leitzinger used Defendants' AMP data rather than transactional data to estimate overcharges

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<sup>135</sup> "The Uniform System of Classification (USC)," <https://perma.cc/RE6C-SDJ4>.

<sup>136</sup> See Tr. of Daubert Hr'g (Oct. 8, 2024) at 165:23-166:7 [MDL Doc. No. 3123].

<sup>137</sup> See DPPs' Mem. Opp'n Mot. Exclude Leitzinger at 12-13, No. 16-CM-27241 [Doc. No. 110]; DPPs' Mem. Opp'n Mot. Exclude Leitzinger at 12-13, No. 16-CB-27241 [Doc. No. 163].

because AMP data better captures chargebacks, rebates, and other price concessions that are sometimes recorded months after an underlying purchase.

*Daubert* does not require that an expert use Defendants' preferred data or the best available data to be reliable—it requires that an expert have “good grounds” to use such data in their methodology.<sup>138</sup> Further, the question for the court is to determine what experts in a discipline find reliable, and if an expert avers that his testimony is based on a type of data on which experts reasonably rely, that is generally enough to survive a court’s inquiry.<sup>139</sup>

Dr. Leitzinger’s use of IQVIA and AMP data to calculate overcharges in Stage Two of his regression analysis is reliable. Accounting for Defendants’ criticisms, Dr. Leitzinger reconfigured his regression analysis to use Defendants’ data rather than averaged AMP data. Results bear out that the difference between Dr. Leitzinger’s model using AMP data and actual transaction data is not meaningful.<sup>140</sup> Further, Dr. Leitzinger performs analysis in his rebuttal report to confirm that IQVIA prices and AMP prices are correlated with one another and justify the use of that data in his model.<sup>141</sup> Dr. Leitzinger’s use of AMP and IQVIA data at this stage of his regression analysis does not render his opinions unreliable just because Defendants would have him use another data set. Whether they find that his analysis is weakened for use of that data, their criticisms go to the weight of his opinion. Dr. Leitzinger, however, demonstrated that

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<sup>138</sup> *Paoli*, 35 F.3d at 742.

<sup>139</sup> *Id.* at 747.

<sup>140</sup> Leitzinger Expert Rebuttal Report ¶¶ 20, 55, No. 16-CM-27241 [Doc. No. 159-94] (hereinafter “Leitzinger Rebuttal Rep.”).

<sup>141</sup> Leitzinger Rebuttal Rep. ¶¶ 26-27, 46, 48 (“In short, it is reasonable and reliable to use the IQVIA data as I did. Certainly, the many studies that have used IQVIA data over the past 30 years attest to its reasonableness. The fact that it may not provide information that allows one to parse pricing along all of the specific dimensions that Dr. Johnson has enumerated, does not undermine its usefulness for measuring the market effects relevant to my analysis.”).

the results of his model remained unchanged regardless of which data set he employed, implying that the inputs for his initial model were not so deficient that they pose a problem of reliability.

Next, Defendants criticize Dr. Leitzinger's model and use of AMP data because they say it relies on averaging and does not appropriately account for individual negotiations. Averaging is suspect where it risks masking data, but it can be acceptable where there are other indicia that an expert's average does *not* conceal the truth of the data.<sup>142</sup>

Here again, Dr. Leitzinger's test of Defendants' transaction data demonstrates the reliability of his model, showing that there is little likelihood that his use of AMP data skewed the outcome of his regression. Because the averaging inherent in AMP data did not produce different results from his model with AMP data, there is sufficient basis to say that AMP data did not mask the truth of the data.

Finally, Defendants challenge the statistical significance and internal consistency of Dr. Leitzinger's model. Stage Two of Dr. Leitzinger's regression derives coefficients for each independent variable, which "represent[] the relative impact of that variable on AMP."<sup>143</sup> The coefficients for some of the variables in this regression demonstrate a phenomenon referred to as "switching sign" for both clomipramine and clobetasol.<sup>144</sup> According to Defendants, these sign switches are clear indications of internal inconsistency and the lack of statistical significance in Dr. Leitzinger's model. For example, in some instances Dr. Leitzinger's model demonstrates positive relationships between the costs and prices for one formulation or strength of a drug, but show *negative* relationships between cost and price factors for another formulation or strength of

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<sup>142</sup> See *In re Processed Egg Prods.*, 81 F. Supp. 3d at 428.

<sup>143</sup> Defs.' Mem. Supp. Mot. Exclude Leitzinger at 12, No. 16-CM-27241 [Doc. No. 94].

<sup>144</sup> *Id.* at 13.

that same drug.<sup>145</sup> Defendants contend that, if Dr. Leitzinger's model was reliable, signs for both formulations and strengths of those drugs would be consistent. At bottom, Defendants argue that Dr. Leitzinger's results make little economic sense, both due to the supposed inconsistency of his results and because they posit that his model incorrectly assumes a relationship between IQVIA prices and AMP.

The Court's responsibility at *Daubert* is only to consider whether an expert demonstrates good grounds for their opinion and to question the methods, not outcome, of their models.<sup>146</sup> Parties are called upon to prove only that the assessments in their experts' reports are reliable, not that they are correct.<sup>147</sup> If an expert's methodology and reasoning are sufficiently reliable, the trier of fact must later assess the weight of the expert's conclusions.<sup>148</sup>

Dr. Leitzinger provides good grounds to explain the reliability of sign switching in the results of his model. Dr. Leitzinger asserts that the lack of statistical significance for cost and market factors coefficients in his model is crucial to demonstrate that neither market conditions nor cost can explain price spikes for the bellwether drugs.<sup>149</sup> As Dr. Leitzinger explains,

The absence of statistically meaningful price effects associated with market factors and costs (for most of the bellwether formulations) is not hard to understand and does not in any way undercut the validity of the regression model or the data used in it. If indeed, as Plaintiffs claim in this case, we assume (a) a conspiracy among manufacturers of these drugs to impose artificial price increases of as much as 2,700 percent; and (b) that the co-conspirators did not separately adjust those greatly inflated prices to account for cost changes or market factors that might have moved the needle by 10 percent in a competitive world, there would not be any price movement during the conspiracy period

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<sup>145</sup> See, e.g., *id.* at 13-14 (“For example, focusing on the relationship between cost and AMP prices for Clomipramine, the regression shows a positive relationship between costs and price for the 25 mg and 75 mg strengths (meaning as costs increase, price increases), but the model shows a negative relationship between costs and price for the 50mg strength (as costs increase, price decreases).”).

<sup>146</sup> *Paoli*, 35 F.3d at 742.

<sup>147</sup> *Id.* at 744.

<sup>148</sup> *In re TMI Litig.*, 193 F.3d at 665.

<sup>149</sup> DPPs' Mem. Opp'n Mot. Exclude Leitzinger at 14, No. 16-CM-27241 [Doc. No. 110]; DPPs' Mem. Opp'n Mot. Exclude Leitzinger at 14, No. 16-CB-27241 [Doc. No. 163].

that correlates with changes in cost or market factors. In that case, the regression would not find a meaningful relationship between those normal market factors and prices. That is, **the lack of statistical significance does not show that the regression is unreliable.** Rather, **it is consistent with and supports Plaintiffs' allegations in this case**, that the Price Spikes were not due to cost or other market forces changing, but due to the alleged conspiracy.<sup>150</sup>

Rather than demonstrating a flaw in his model, Dr. Leitzinger affirms that the lack of statistical significance in his model supports his conclusions.

Defendants argue that Dr. Leitzinger's rationalization of his results proves their point and that "one could always claim that a failure to model supply and demand factors is evidence that something other than supply and demand (e.g., conspiracy) explains pricing."<sup>151</sup> But it is this precise disagreement that demonstrates how their arguments regarding Dr. Leitzinger's model on this point are better fit for cross-examination and criticism from Defendants' experts than it is for a *Daubert* motion. It is not the Court's role under *Daubert* to determine the merits of an expert's findings or to resolve disagreements between experts.<sup>152</sup> To the extent that Defendants disagree with Dr. Leitzinger's rationalization of his results, their criticisms go to the weight of his opinions.

## 2. Comcast Issue

Defendants argue that Dr. Leitzinger's opinions are irrelevant in these cases because his overcharge model is not sufficiently tied to the DPPs' theory of antitrust impact. For a damages model to be relevant, Defendants argue that the Supreme Court's decision in *Comcast Corp. v.*

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<sup>150</sup> Leitzinger Rebuttal Rep. ¶ 83 (emphasis added).

<sup>151</sup> Defs.' Mem. Supp. Mot. Exclude Leitzinger at 16, No. 16-CM-27241 [Doc. No. 94].

<sup>152</sup> *In re TMI Litig.*, 193 F.3d at 665; *Brand Design Co., Inc. v. Rite Aid Corp.*, No. 22-1174, 2024 WL 643141 (E.D. Pa. Feb. 14, 2024).

*Behrend* dictates that the expert's model must "isolate damages resulting from any one theory of antitrust impact."<sup>153</sup>

In *Comcast*, plaintiffs proposed four separate theories of antitrust impact to certify a class of Comcast subscribers under Rule 23(b)(3) for alleged damages of federal antitrust laws.<sup>154</sup> In contrast, DPPs assert one theory of antitrust impact; that is, a conspiracy to increase prices resulting in a single theory of antitrust injury.<sup>155</sup> For this reason and for the reasons stated in the Court's ruling relating to the experts in the EPPs' bellwether cases,<sup>156</sup> *Comcast* does not provide a basis for excluding Dr. Leitzinger's opinions under *Daubert* at this stage of the litigation.

### 3. Opinions Not Based on Scientific Methodology

Defendants argue that two of Dr. Leitzinger's opinions are unreliable because they are not based in scientific methodology or Dr. Leitzinger's specialized knowledge. On this point, Defendants point to two aspects of Dr. Leitzinger's opinions: (1) that purchasers from Taro Pharmaceuticals suffered injury and (2) that the presentation of an alternative overcharge calculation.

#### *Taro Pharmaceuticals Purchasers*

Following his Stage Two model, Dr. Leitzinger calculates the total overcharges for each bellwether drug by "multiplying the annual percentage overcharge by the corresponding

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<sup>153</sup> 569 U.S. 27, 38 (2013).

<sup>154</sup> *Id.* at 30-31.

<sup>155</sup> *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 967 F.3d 264, 271 n.11 (3d Cir. 2020) ("This case is unlike *Comcast* because there is only one theory of antitrust injury, and that theory corresponds to a theory of liability."). See also *In re Urethane Antitrust Litig.*, 166 F. Supp. 3d 501, 511 (D.N.J. 2016) (holding that, even if *Comcast* does apply to admissibility of an expert in a Court's analysis of *Daubert*, a case is distinguishable where there is a single theory of antitrust impact and the expert's model does not seek to measure damages stemming from a rejected model).

<sup>156</sup> See *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, 2024 WL 4980784 at \*9 (E.D. Pa. Dec. 3, 2024).

clomipramine and clobetasol purchases reflected in the transaction data produced for these drugs.”<sup>157</sup> But, according to Dr. Leitzinger, he did not possess sufficient data on purchases of bellwether drugs from Taro pharmaceuticals to use transactional data.<sup>158</sup> Thus, in his initial expert report, Dr. Leitzinger relied on limited invoice data as well as IQVIA data to estimate total overcharges for 27 purchasers of the bellwether drugs from Taro Pharmaceuticals.<sup>159</sup> According to Dr. Leitzinger, at least some of the prices within those invoices include prices below Wholesale Acquisition Cost (“WAC”)<sup>160</sup> and therefore reflect at least some discounting, which supports his findings. Further, Dr. Leitzinger notes that invoice prices for all buyers exceed non-conspiracy prices levels by statistically significant amounts.<sup>161</sup>

In addition to invoice and IQVIA data, Dr. Leitzinger draws inferences that direct purchasers were overcharged flowing from Defendant Taro’s conduct given additional circumstantial factors, including Taro’s July 23, 2020 Deferred Prosecution Agreement (“DPA”) with the U.S. Department of Justice,<sup>162</sup> wherein:

[Taro] admits, accepts, and acknowledges that … [Taro officers and employees] conspired with other individuals and entities engaged in the manufacture and sale of generic drugs to suppress and eliminate competition by agreeing to allocate customers and rig bids for, and/or stabilize, maintain, and fix prices of certain generic drugs sold in the United States …From in or about March 2013 and

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<sup>157</sup> Leitzinger Rep. ¶ 52.

<sup>158</sup> *Id.* ¶ 52 n. 64.

<sup>159</sup> *Id.* at ¶¶ 52, 58.

<sup>160</sup> Dr. Leitzinger explains that WAC is the manufacturer’s list price. *Id.* ¶ 12.

<sup>161</sup> *Id.* ¶ 59(e) (“that is, if one performs the impact analysis described above for the other Clomipramine and Clobetasol Class members using the invoice prices available for the Taro buyers, they would all show statistically significant overcharges.”)

<sup>162</sup> In addition to the Taro DPA, Dr. Leitzinger indicates that he relied on “[the fact that] Taro initiated the list Price Spikes described above for both drugs,” “Taro’s AMPs for both clomipramine and clobetasol (which reflect discounts and rebates off list prices) spiked in a similar fashion to its list prices--Taro’s AMP prices for clomipramine were the highest of any Clomipramine Defendant,” “At least some of the invoice prices for all 27 of these Taro buyers include prices that were below concurrent list (WAC) prices and therefore already include some, if not all, discounting,” and “invoice prices provided for these 27 buyers all exceed nonconspiracy price levels by statistically significant amounts....” *Id.* at ¶ 59 (b)-(e).

continuing until in or about December 2015, Taro U.S.A. conspired to suppress and eliminate competition by agreeing to allocate customers and rig bids for, and stabilize, maintain, and fix prices of, certain generic drugs in the United States, including clobetasol (cream, emollient cream, gel, ointment, and solution), desonide ointment, and nystatin triamcinolone cream, with Sandoz Inc. (“Sandoz”)...<sup>163</sup>

In his rebuttal report, Dr. Leitzinger incorporates additional transactional data produced by Taro and employs Defendants’ expert’s rules regarding transaction types to prepare alternative overcharge estimates.<sup>164</sup>

Defendants argue that Dr. Leitzinger does not base his opinions on Taro-only purchasers on a methodology beyond his own intuition.<sup>165</sup> The Court’s *Daubert* analysis requires that an expert present “good grounds” for their opinion.<sup>166</sup> To demonstrate reliability, an expert’s methodology must be “based on the methods and procedures of science, not on subjective belief and unsupported speculation.<sup>167</sup> Experts need not, however, present the best grounds or unflawed methods.<sup>168</sup>

The Court agrees with Defendants that Dr. Leitzinger’s initial report may not have satisfied *Daubert* standards. The limited data on which he relies and his own expertise to draw inferences are questionable grounds to assert that Taro-only purchasers suffered injury. Such an inquiry must be based in a rigorous analysis to be reliable.

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<sup>163</sup> *Id.*; *United States of America v. Taro Pharmaceuticals U.S.A., Inc.*, No. 20-cr-214, Deferred Prosecution Agreement, ¶ 2 and Attachment A [Doc. No. 2] (E.D. Pa. July 23, 2020).

<sup>164</sup> Leitzinger Rebuttal Rep. ¶19.

<sup>165</sup> Defs.’ Mem. Supp. Mot. Exclude Leitzinger at 24, No. 16-CM-27241 [Doc. No. 94] (citation omitted).

<sup>166</sup> *Paoli*, 35 F.3d at 742.

<sup>167</sup> *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 833-34 (3d Cir. 2020) (citations omitted).

<sup>168</sup> See *Holbrook.*, 80 F.3d at 784; *Paoli*, 35 F.3d at 744–45.

DPPs argue that an expert's initial, insufficient analysis may still be reliable for class certification if that expert responds to criticism and their findings are largely unchanged.<sup>169</sup> The Court agrees with DPPs that any deficiency in Dr. Leitzinger's initial report is cured by the more robust analysis using Defendants' transactional data in his rebuttal report. The parties disagree about why Dr. Leitzinger did not initially possess Defendants' transactional data, but that dispute is moot. Once Dr. Leitzinger obtained the data, he performed additional analysis and, notably, the results between the two models remained virtually unchanged.

Dr. Leitzinger's determination in his initial report regarding Taro-only purchasers is reliable, as demonstrated by findings in his rebuttal report. To the extent that Defendants wish to highlight the deficiency in Dr. Leitzinger's initial findings, that argument is appropriate on cross-examination and goes to the weight of his opinions.

#### *Alternative Overcharges*

Defendants also allege that the alternative overcharges model in Dr. Leitzinger's report is "based on an unscientific approach that simply assumes that prices would have remained unchanged throughout the relevant time period."<sup>170</sup> Dr. Leitzinger provides a description of this analysis:

Accordingly, assuming no conspiracies, one could simply (and with some validity as an economic matter) model prices by removing the obvious increases associated with the Price Spikes and their aftermath and in that way continue the low and stable price level which preceded those Price Spikes for both drugs. Overcharges would then reflect the difference in prices at each point in time between the low pre-conspiracies price level and the Price Spikes.... I also present overcharges by removing the increases associated with the Price Spikes by continuing the low and stable price level which preceded the Price

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<sup>169</sup> DPPs rely on *In re: Domestic Drywall Antitrust Litigation*, 322 F.R.D. 188, 228-29 (E.D. Pa. 2017), in which the court chose not to exclude an expert in part because that expert had sufficiently addressed criticisms of his initial report in a subsequent reply report.

<sup>170</sup> Defs.' Mem. Supp. Mot. Exclude Leitzinger at 25, No. 16-CM-27241 [Doc. No. 94].

Spikes for both drugs. Overcharges would then reflect the difference between the low price levels prior to the conspiracies and the prices after the Price Spikes.<sup>171</sup>

The Court's inquiry in a *Daubert* analysis is flexible, but to demonstrate reliability, an expert's methodology must be "based on the methods and procedures of science, not on subjective belief and unsupported speculation."<sup>172</sup> Here, Dr. Leitzinger's opinion is speculative. It is not enough, as DPPs suggest, that Dr. Leitzinger asserts based on his observation of previous years that prices would probably remain unchanged without the conspiracy. Dr. Leitzinger does not perform calculations or econometric analysis to support his opinions. DPPs are correct that an expert may construct a but-for world to use as a comparative,<sup>173</sup> but that expert must still offer good grounds for the calculation of that offense-free world. Dr. Leitzinger's alternative overcharge calculations are not reliable and are thus excluded.

Defendants' motion to exclude the opinions of Dr. Leitzinger are partially granted, as his opinions relate to his alternative overcharge calculations.

#### **D. Conclusion**

DPPs' motion to exclude the opinions of Dr. Gilbert is **DENIED** in part and **GRANTED** in part as it relates to testimony by Dr. Gilbert that economic evidence has no bearing on determining the difference between legal and illegal interdependent conduct.

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<sup>171</sup> Leitzinger Rep. ¶¶ 30, 53.

<sup>172</sup> *Paoli*, 35 F.3d at 742 (expert testimony does not have good grounds if subjective or speculative); *UGI Sunbury*, 949 F.3d at 833-34 (citations omitted).

<sup>173</sup> See, e.g., *LePage's Inc. v. 3M*, 324 F.3d 141, 165 (3d Cir. 2003).

Defendants' motion to exclude the opinions of Dr. McGuire is **DENIED** in part and **GRANTED** in part to the extent that Dr. McGuire opines that his conditional probability test demonstrates the existence of a "super" plus factor.

Defendants' motion to exclude the opinions of Dr. Leitzinger is **DENIED** in part and **GRANTED** in part as his opinions relate to his alternative overcharge calculations.